(h) CCER instructions and a service life plan must be provided to purchasers. This document must be clearly written.

(1) Instructions must address the following topics and elements:

(i) An explanation of how the CCER works;

(ii) A schematic diagram of the CCER;

(iii) Procedures for donning and use;

(iv) Procedures for inspecting the operating condition of the CCER;

(v) Procedures and conditions for storage, including but not limited to any recommended minimum and maximum temperatures for storage;

(vi) Limitations on use, including but not limited to any recommended minimum and maximum temperatures for use;

(vii) Procedures for disposal; and

(viii) Procedures for registration of the unit with NIOSH, pursuant to § 84.311.

(2) The service life must be addressed covering at least the following topics:

(i) The maximum number of years, from the date of manufacture, that the unit may remain available for use; this limit is intended to prevent the continued use of a unit that the applicant cannot assure would continue to perform as approved by NIOSH, due to reasonably foreseeable degradation of materials used in its construction;

(ii) Any other conditions, other than that specified under paragraph (h)(2)(i) of this section, that should govern the removal from service of the CCER (including an indication given by the activation or operation of any required indicator showing the monitored condition has occurred); and

(iii) Any procedures by which a user or others should inspect the CCER, perform any maintenance possible and necessary, and determine when the CCER should be removed from service.

(i) Each individual CCER unit approval label shall identify the capacity rating and number of liters of oxygen as determined by the capacity testing, pursuant to § 84.304.

§ 84.303 General testing conditions and requirements.

(a) NIOSH will conduct capacity and performance tests on the CCER using a breathing and metabolic simulator to provide quantitative evaluations and human subjects on a treadmill to provide qualitative evaluations. Information on the design and operation of the simulator is available from the NIOSH Web site at *http://www.cdc.gov/niosh/npptl*. Technical specifications can be obtained from NIOSH by contacting the National Personal Protective Technology Laboratory (NPPTL) by mail: P.O. Box 18070, 626 Cochrans Mill Road, Pittsburgh, PA 15236. Telephone: 412–386–4000 (this is not a toll-free number). Email: *npptl@cdc.gov*.

(b) Capacity, performance, and wearability tests will continuously monitor the stressors listed in Table 1. The stressors and their respective acceptable ranges will be measured at the interface between the CCER and the mouth by instruments capable of breath-by-breath measurement. Stressor measurements will be evaluated as 1-minute averages. The operating averages of each stressor will be calculated upon the completion of each test as the average of the 1-minute measurements of the stressor recorded during the test. The level of any excursion for a stressor occurring during a test will be defined by the 1-minute average value(s) of the excursion(s).

TABLE 1—MONITORED STRESSORS AND THEIR ACCEPTABLE RANGES

Stressor	Acceptable range operating average	Acceptable range excursion
Average inhaled CO_2	<1.5%	≤4%.
Average inhaled O_2	>19.5%	≥15%.
Peak Breathing Pressures	$\Delta P \leq 200$ mm H_2O	$-300 \leq \Delta P \leq 200$ mm H_2O.
Wet-bulb temperature[1]	<43 °C	≤50 °C.

[1] Wet-bulb temperature is a measurement of the temperature of a wet surface. It represents the temperature of the inhaled breathing gas in the CCER user's trachea.

(c) Capacity and performance tests will conclude when the stored breathing gas supply has been fully expended.

(d) NIOSH will determine a CCER to have failed a capacity, performance, or wearability test if any of the following occurs:

(1) A 1-minute average measurement of any stressor listed in Table 1 occurs outside the acceptable excursion range specified in Table 1; or an average stressor measurement calculated at the completion of a performance or capacity test exceeds the acceptable operating average range specified in Table 1; or

(2) A human subject cannot complete the test for any reason related to the CCER, as determined by NIOSH.

(e) Unless otherwise stated, tests required under this subpart will be conducted at the following ambient conditions:

(1) Ambient temperatures of 23 °C ±3 °C; and

(2) Atmospheric pressures of 735 mm Hg ±15 mm Hg.

§ 84.304 Capacity test requirements.

(a) NIOSH will conduct the capacity test on a total of 8 to 10 of the units submitted for approval, as follows:

(1) Three units will be tested on a breathing and metabolic simulator in the condition in which they are received from the applicant;

(2) Two units will be tested on a breathing and metabolic simulator after being subjected to the environmental treatments specified in § 84.307 of this subpart;

(3) Two units will be tested on a breathing and metabolic simulator at the cold-temperature limit recommended by the manufacturer under § 84.302(h)(1), after the unit has been stored for a minimum of 24 hours at this limit; and

(4) One unit, in the condition in which it is received from the applicant, will be tested by a human subject on a treadmill.

(5) To approve a CCER for use in coal mines, two units will also be tested by a human subject under the specifications of §§ 84.99 and 84.100 that are applicable to man test 4.

(b) The capacity test will begin upon the first inhalation from or exhalation into the unit.

(c) Each unit will be tested at a constant work rate, depending on the capacity value specified by the manufacturer, according to the requirements specified in Table 2. All volumes are given at standard temperature (0 C) and pressure (760 mm Hg), dry, unless otherwise noted.

(d) NIOSH will rate an approved CCER using the appropriate capacity rating, as specified in Table 2.

TABLE 2—CAPACITY TEST REQUIREMENTS

Capacity rating	Capacity (L of O_2)	VO_2 (L/min)	VCO_2 (L/min)	Ve (L/min)	RF (Breaths/min)
Cap 1	20 ≤L ≤59	2.50	2.50	55	22
Cap 2	60 ≤L ≤79	2.00	1.80	44	20
Cap 3	L ≥80	1.35	1.15	30	18

VO_2 = volume of oxygen consumed per minute; VCO_2 = volume of carbon dioxide produced per minute.
Ve = ventilation rate in liters of air per minute; RF = respiratory frequency.

(e) NIOSH will document the least value achieved by the seven units tested using the breathing and metabolic simulator. NIOSH will quantify this value of achieved capacity within an increment of 5 liters, rounding intermediate values to the nearest lower 5-liter increment.

§ 84.305 Performance test requirements.

(a) NIOSH will conduct the performance test on a total of six of the units submitted for approval, as follows:

(1) Three units will be tested on a breathing and metabolic simulator in the condition in which they were received from the applicant; and

(2) Two units will be tested on a breathing and metabolic simulator